

PATIENT GROUP DIRECTION (PGD) FOR		
PGD 217 (S)	LIDOCAINE HYDROCHLORIDE 2%, AND CHLORHEXIDINE GLUCONATE ANAESTHETIC 0.25% GEL (Instillagel) Sexual Health Patients aged 13 years and older	P

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD
BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**

PROFESSIONAL(S) TO WHICH THIS PGD APPLIES:

Registered nurse working in Integrated Sexual Health Service (ISHS) who has received training relating to the use/content of this direction.

CLINICAL CONDITION	
Indication	<ul style="list-style-type: none"> Anaesthesia prior to undertaking intrauterine techniques. Patients presenting with an acute painful attack of Genital Herpes* <p>*Additional information during Covid outbreak: Nurses using this PGD to provide medication will be exempt from usual PGD conditions, i.e. they will not need to see patients Face to Face nor examine the patients and may delegate supply to another registered nurse. The nurse undertaking the remote/virtual consultation MUST prepare the medicine for dispatch/supply under the PGD, but can delegate the responsibility of handing over the medicine to another registered nurse.</p>
Inclusion Criteria	<ul style="list-style-type: none"> Patients aged 13 years and above presenting with the above indications. Patients with a laboratory confirmed diagnosis of genital herpes who have symptoms of an incipient attack.
Exclusion Criteria	<ul style="list-style-type: none"> Children < 13 years Patients lacking capacity to treatment Reservations/concerns by patient about side effects of the treatment. Known hypersensitivity to the active ingredients (amide-type anaesthetics, chlorhexidine and alkylhydroxybenzoates) or any of the excipients
Cautions/Need for Further Advice	<ul style="list-style-type: none"> Acute porphyrias Epilepsy Hepatic, renal or respiratory impairment Impaired cardiac conditions Myasthenia gravis Shock

	<ul style="list-style-type: none"> Breastfeeding – present in milk but amount too small to be harmful Pregnancy – avoid during the first 3 months of pregnancy unless absolutely necessary Concurrent medication - Check all concurrent medication with the patient and in the current BNF before using lidocaine gel. Refer to a doctor if the patient is taking any medication which may interact with the intended treatment, particularly anti-arrhythmic drugs. The current BNF can be accessed in either its paper format or electronic format using the hyperlink http://www.bnf.org
Action if Patient Declines or is Excluded	<p>If a patient is excluded refer to a doctor or ISHS non-medical prescriber. Consider alternative treatment. Document advice given.</p> <p>If a patient declines treatment or referral, document full discussion in patient's records.</p>

DRUG DETAILS	
Name, Form & Strength of Medicine	Lidocaine Hydrochloride 2%, Chlorhexidine Gluconate Solution 0.25% Gel in 11ml syringe.
Route/Method	<p>Intrauterine techniques Gel to be instilled slowly into the cervical canal and onto the surface of the cervix at the site of the tenaculum/allis placement using the appropriate quill prior to insertion.</p> <p>Genital herpes Direct topical application to affected areas.</p>
Off-label Use	<p>Acute painful attack of genital herpes is an off-label indication.</p> <p>Repeated use of an opened syringe for genital herpes is off-label.</p>
Dosage/Frequency	<p>Intrauterine techniques Single application for each procedure</p> <p>Genital herpes Apply a quantity sufficient to cover the affected sore area(s) only when required</p>
Quantity	<p>Intrauterine techniques ONE 11ml syringe for each procedure</p> <p>Genital herpes A maximum of TWO 11ml syringes can be issued to the patient</p>

<p>Total Daily Dose</p>	<p>Intrauterine techniques One dose</p> <p>Genital herpes Advise patient not to use more than ONE 11ml syringes per day</p>
<p>Duration of Treatment</p>	<p>Intrauterine techniques Single dose for procedure</p> <p>Genital herpes Maximum of 1 week. The patient should then be reviewed if they still have ongoing symptoms.</p>
<p>Advice to Patient/Carer</p>	<p>For all indications, explain treatment and side effects.</p> <p>Read the patient product information leaflet supplied before use. <i>Sensitively ensure patient is able to read and understand, if not then cover verbally.</i></p> <ul style="list-style-type: none"> • A slight stinging may be felt on application of gel • The anaesthetic effect takes between 3 – 5minutes to work following application • Monitor for sensitivity reaction • Systemic side effects (e.g.lightheadedness, paraesthesia) may occur with excessive absorption • Seek advice if unable to pass urine • Gel can be used prior to micturition or defecation if painful • Wash hands before and after using the product • Squeeze a suitable amount on to the finger for application. Do not apply the syringe directly to ulcers • Each disposable syringe only be used for up to a maximum of 3 days after opening – discard remainder and use a new tube if further treatment is required. • Advise saline baths to relieve discomfort/pain • If symptoms persist for more than one week, arrange to see a non-medical prescriber or a doctor • Contact or re-attend clinic in the event of any adverse outcome
<p>Advice to Staff</p>	<p>Gillick Competence Patients aged < 16 years should be assessed for Gillick competence following the Under 18 Checklist</p> <p>Safeguarding: Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record.</p> <p>DCHS: Safeguarding adults and children policies on DCHS share point. DCHS Safeguarding Team: 01773 850000. Update with info for sexual health as per national PGD's</p> <p>Rapid and extensive absorption may result in systematic side effects, confusion, respiratory depression, convulsions, hypotension and bradycardia</p>

	<p>(may lead to cardiac arrest). If this occurs, then immediate medical advice should be sought.</p> <p>The administration of medication should comply with standard infection control practices e.g. hand hygiene, Aseptic Non-Touch Technique and waste disposal. These policies can be found on the DCHS Policies and Procedures section of the Intranet.</p> <p>Explain treatment, side effects and advice above.</p> <ul style="list-style-type: none"> • Specific advice for genital herpes • Advise patient this is an off-label indication and usage in this way will not be described within the accompanying patient information leaflet. <p>Self-Check: correct product, dose selected and check expiry date.</p>
Record	<ul style="list-style-type: none"> • Patient's name, address, date of birth • Assessment to competency to consent (including Gillick competency) to treatment for patients at risk • Any discussion with doctor/ another professional e.g. regarding safeguarding • Verbal consent obtained as per DCHS Consent Policy • Allergies • Drug, dose, quantity supplied • Expiry details • Practitioner's identifier • Advice given to patient (including side effects, contraception etc) • Referral arrangements (including self-care) • Any other relevant details of consultation

CHARACTERISTICS OF STAFF	
Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	<p>Has undertaken the local training programme on the process, responsibilities and scope of PGDs.</p> <p>Has undertaken local training based on the use of this PGD.</p> <p>Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the last 12 months.</p>
Continuing Training & Education	The clinician should be aware of any change to the recommendations for the medicines listed.

	<p>It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.</p> <p>Evidence of Continuing Professional Development in ISHS nurse role. Completion of BASHH competencies and Sexually Transmitted Infections Foundation (STIF) course.</p>
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REFERRAL ARRANGEMENTS AND AUDIT TRAIL	
Referral Arrangements	The clinician is expected to use their clinical judgment and refer patients to an appropriate senior or medical doctor for advice and management as they see fit.
Records/Audit Trail	<ul style="list-style-type: none"> • Document in Patient's record • Record PGD use

ADDITIONAL INFORMATION	
References	<ol style="list-style-type: none"> 1. British National Formulary http://www.bnf.org 2. Summary of product characteristics https://products.mhra.gov.uk/ 3. Link for Medicines Code: Medicines Code policy 4. http://www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines 5. Integrated Sexual Health Handbook 6. BASHH (British Association of Sexual Health and HIV) guidelines 7. Faculty of Sexual and Reproductive Health Care 8. UK MEC Eligibility Criteria for Contraceptive Use
Storage	<p>Medicines must be stored securely according to national guidelines and in accordance with the product SPC.</p> <p>However, in the event of an inadvertent or unavoidable deviation of temperature follow the Temperature Monitoring of Medicines Storage Rooms SOP.</p>
Drug Interactions	<p>Comprehensive lists of drug interactions are not described in each PGD, only the most significant are listed. Chlorhexidine has no significant drug interactions. A detailed list of drug interactions for lidocaine is available from the eBNF www.bnf.org.</p>
Identification & Management of Adverse Reactions	<p>Common is significant side effects are listed with the advice given to the patient/carer.</p> <p>A detailed list of associated adverse reactions is available from the eBNF (www.bnf.org).</p>

Management of and Reporting Procedure for Adverse Reactions	<ul style="list-style-type: none"> Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Record all adverse drug reactions (ADRs) in the individual's medical record Report any adverse reactions via DCHS incident policy.
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PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP

This PGD has been developed and agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from all three trusts stated below for use within Integrated Sexual Health Services (ISHS)

Chesterfield Royal Hospital Foundation Trust (CRHFT), Derby Teaching Hospitals Foundation Trust (DTHFT) Trust and Derbyshire Community Health Services Foundation Trust (DCHSFT)





Name	Position
Dr Fatima Nathani	Lead Clinician - DCHSFT
Dr Ade Apoola	Consultant - DTHFT
Dr Anura Piyadigamage	Consultant - CRHFT
Anna Braithwaite	Chief Pharmacist – DCHS
Sharon Boden	Senior Sister - County

Review		
Date & Comments	Name	Position
January 2021 Minor change – addition of Covid information.	Emily Stelmach	Advanced Pharmacist
March 2022 <ul style="list-style-type: none"> Acute porphyria added as caution Rewording to distinguish conditions of use for the two separate indications Addition of off-label section. Review of the use of Instillagel for genital herpes 	Ben Dorward Sharon Boden	Advanced Pharmacist Quality Manager, ISHS

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on 24 March 2022

This PGD is authorised for use on behalf of DCHS by the following signatories.

Position of signatory	Name	Signature	Date
Deputy Chief Nurse	Jo Hunter		14/04/2022
Head of Medicines Management	Kate Needham		14/04/2022
Medical Director	Dr Ben Pearson		14/04/2022
Lead Clinician	Dr Ade Apoola		14/04/2022

PRACTITIONER AUTHORISATION SHEET

PGD: 217S – Lidocaine and Chlorhexidine Gel

Version & Expiry Date: v7, Expiry 31 March 2025

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.